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CANADIAN SENIORS AND PUBLICLY FUNDED ACCESS TO DRUGS

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INTRODUCTION

Pharmaceuticals, available to Canadians as prescription or over-the-counter drugs, play a significant role in health care. Drug products offered as treatment or as prevention for diseases or symptoms can have a considerable effect on the quality and length of life. When available and when used appropriately, such products can prevent ill-health or provide effective treatment of certain illnesses. They can relieve disability, replace more invasive surgical procedures, and reduce hospitalization.

Seniors (defined as people aged 65 years of age and over), as a group, have a higher prevalence than other parts of the population of many chronic health problems such as heart disease, diabetes, arthritis and cancer. The effort to manage these conditions with pharmaceuticals makes seniors the largest per-capita consumers of drugs in Canada.

According to Statistics Canada, the majority of seniors take some form of drug for health reasons. In 1999, over 80% of people aged 65 and over living at home reported that they had been diagnosed with at least one chronic health condition and took some form of prescription or over-the-counter medication.(1) Moreover, the proportion of seniors that report using five or more drugs is increasing.(2)

The following discussion considers several factors that affect Canadian seniors' ability to access drugs for health reasons. First, it provides an overview of the publicly funded drug plans that facilitate access through coverage provided by federal, provincial and territorial governments. It then looks at the role that these insurance plans play in ensuring that drugs approved through the regulatory process are listed on the drug plan formularies and available when seniors need them. Finally, it assesses some of the costs of drug treatment that may fall to seniors in spite of the drug plans.

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(1) Statistics Canada, *A Portrait of Seniors in Canada*, 3rd ed., 89-519-XPE, Ottawa, 1999, p. 62.

(2) Canadian Institute for Health Information, *Health Care in Canada*, Ottawa, 2002, p. 81.

PUBLICLY FUNDED PLANS AND DRUG COVERAGE

In Canada, universal coverage for all medically necessary services provided by physicians or in hospitals has been in place since 1971. The *Canada Health Act* of 1984 continued the requirement for coverage for the general population through federal/provincial/territorial cost sharing applicable to hospital and physician services.

However, while the costs of prescription and non-prescription drugs consumed in hospitals are covered, those used outside of hospitals are not. Seniors and other Canadians must pay for drugs out of their own pockets unless the drug is covered by a federal, provincial or territorial drug plan or a private insurance drug plan. Under both the publicly funded and the private drug plans, there is wide variation in design, eligibility criteria and the potential for out-of-pocket costs.

The federal, provincial and territorial governments offer assorted drug coverage plans for older Canadians. At the federal level, several programs offer coverage for eligible groups of Canadian seniors who cannot access benefits under provincial plans. Thus, the Non-Insured Health Benefits (NIHB) Program administered by Health Canada serves eligible First Nations, Inuit and Innu, of which seniors represent 5.2% of the NIHB total population.(3) These seniors receive NIHB coverage for drug needs not included in provincial or territorial plans.(4) In a similar fashion, the Prescription Drug Program of Veterans Affairs Canada serves eligible clients, consisting primarily of war service veterans and former members of the Canadian Forces and the Royal Canadian Mounted Police who have a pensioned condition. Veterans seeking treatments unrelated to a pensioned condition may also be eligible for coverage if they cannot access the provincial programs available to them and if they have a clearly demonstrated health need.(5)

At the provincial and territorial level, seniors are the group most likely to benefit from targeted governmental drug programs. However, as Table 1 shows, the range and extent of the coverage vary from one province and territory to another. In some instance, coverage is directed specifically to seniors; in others, seniors are eligible for coverage on the same basis as

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(3) Health Canada, Non-Insured Health Benefits Program Annual Report 2002-2003, Ottawa, 2003, p. 10, http://www.hc-sc.gc.ca/fnihb/nihb/annualreport/annualreport2002_2003.pdf.

(4) Health Canada, Introduction to the NIHB Drug Benefit List, http://www.hc-sc.gc.ca/fnihb/nihb/pharmacy/drugbenefitlist/Background%20on%20NIHB%20Program.

(5) Veterans Affairs Canada, Prescription Drug Program, http://www.vac-acc.gc.ca/clients/sub.cfm?source=services/poc/poc10.

other parts of the population (i.e., based on family income). In addition, the distribution of seniors across the country is uneven. While the four largest provinces – Alberta, British Columbia, Ontario and Quebec – account for more than 80% of Canadian seniors overall, seniors account for a larger share of the overall population in provinces such as Manitoba and Saskatchewan.

TABLE 1

Provincial and Territorial Drug Plans for Seniors

Province/Territory	General Description
British Columbia	PharmaCare pays seniors' eligible prescription drug costs until they reach their deductible level. The deductible is based on the family's net income. Once they have reached their deductible, Pharmacare pays 75% of the cost of a prescription.(6)
Alberta	Under the province's prescription drug plan, seniors pay 30%, up to a $25 maximum, per prescription or refill. If they choose a more expensive brand-name drug instead of an equivalent generic drug, they pay the additional cost.(7)
Saskatchewan	For seniors living in the community (i.e., not in a special care home) who receive the federal Guaranteed Income Supplement (GIS), the Drug Plan family deductible is $200 semi-annually. Once the $200 deductible is paid, they pay 35% of their prescription costs.(8)
Manitoba	Pharmacare coverage is based on both total family income and the amount paid for eligible prescription drugs. All Manitobans, regardless of age, pay a portion of the cost of their eligible prescription drugs as a yearly deductible. The deductible is based on annual family income.(9)
Ontario	The Ontario Drug Benefit (ODB) program is income-based. The higher income co-payment category includes individual seniors (income more than $16,018 a year) and senior couples (income more than $24,175 per year); people in this category pay the first $100 (deductible) in prescription costs. After that, they may pay up to a maximum of $6.11 (ODB dispensing fee) for each prescription filled in the year. Seniors in the lower income co-payment category may pay up to $2 for each prescription filled.(10)

(6) British Columbia, Fair PharmaCare Plan, http://www.healthservices.gov.bc.ca/pharme/.

(7) Alberta, Health Care Insurance Plan and Services, http://www.health.gov.ab.ca/ahcip/prescription/seniors.html.

(8) Saskatchewan Drug Plan, http://www.health.gov.sk.ca/ps_drug_plan.html.

(9) Manitoba Pharmacare, http://www.gov.mb.ca/health/pharmacare/index.html.

(10) Ontario Drug Benefit, http://www.health.gov.on.ca/english/public/pub/drugs/deduct2.html.

Province/Territory	General Description
Quebec	At 65 years of age, seniors are automatically registered for the Basic Medication Plan if not eligible for a private plan. They pay a yearly premium (varying from $0 to $460 per adult) determined on the basis of net family income. When they purchase insured drugs at a pharmacy, they pay only a portion of their cost. This contribution is established on the basis of the insured person's profile, as determined by the amount of the GIS received each month from the federal government.(11)
New Brunswick	The Prescription Drug Program covers seniors who receive the GIS or who qualify for benefits based on their annual income. Seniors receiving the GIS are required to pay a co-payment charge of $9.05 for each prescription, up to a maximum of $250 in one calendar year. Those seniors who qualify for benefits based on their total annual income are required to pay a co-payment charge of $15 per prescription.(12)
Nova Scotia	Under Pharmacare, seniors pay an annual premium of $390, then a 33% co-payment of the cost of each prescription (a minimum of $3 and a maximum of $30 per prescription) up to an out-of-pocket maximum of $350 per year. A tax credit of up to $300 per year is available to low-income seniors to refund the cost of the premium and co-payments.(13)
Prince Edward Island	The Seniors Drug Cost Assistance Plan provides assistance for the purchase of specified prescription and non-prescription medications for persons who are eligible for P.E.I. Medicare and are 65 years of age or more. The plan provides the first $8 of the medication cost plus the pharmacy professional fee for each prescription.(14)
Newfoundland	The Senior Citizens Drug Subsidy Program provides prescription drug coverage for seniors who receive the GIS and who are registered for Old Age Security benefits. It provides coverage of defined ingredient costs only for identified benefits. Seniors pay the remaining cost of a prescription as a co-payment.(15)

(11) La Régie de l'assurance maladie du Québec, Prescription Drug Insurance Plan, http://www.ramq.gouv.qc.ca/en/citoyens/assurancemedicaments/application/65ansetplus/bilans/prive_n.shtml.

(12) New Brunswick Prescription Drug Program, Seniors Beneficiary Group, http://www.gnb.ca/0212/seniors-e.asp.

(13) Nova Scotia Seniors' Pharmacare Program, http://www.gov.ns.ca/health/pharmacare/pubs/pharmacare_information.pdf.

(14) Prince Edward Island, Drug Programs Formulary, http://www.gov.pe.ca/photos/original/hss_dr_formu_2.pdf.

(15) Newfoundland and Labrador Prescription Drug Program, http://www.gov.nf.ca/health/nlpdp/overview.htm.

Province/Territory	General Description
Yukon	Pharmacare provides drug coverage for persons 65 years of age and over and their spouses 60 years of age and over, whose benefits are not covered by private insurance. It pays the total costs of the lowest-priced generics of all prescription drugs listed in the Yukon Pharmacare Formulary, including the dispensing fee.(16)
Northwest Territories	For seniors, the Prescription Drug Benefits provide up to 100% coverage for eligible prescription drug products when the drug is prescribed by a health care professional and dispensed by a licensed pharmacist.(17)
Nunavut	Drugs for seniors and people on social assistance are 100% covered by the territory.

PUBLICLY FUNDED PLANS AND AVAILABILITY OF DRUGS

Access to drug products that are safe, effective, and high-quality is an important factor for Canadian seniors. The availability of certain products across the country can be affected by governmental and professional regulatory processes aimed at ensuring these characteristics. Various governmental approval processes and professional practice guidelines can enhance or limit the sale, use and insurance coverage of any drug, but they create particular barriers for unproven or innovative therapies.

In Canada, the review of new drugs and the approval for their sale in Canada is a federal responsibility. Once a drug company has tested a drug in different types of clinical trials, it can file a new drug submission with Health Canada, which will assess the product's efficacy and safety. If it approves the drug, Health Canada issues a Notice of Compliance that allows the company to sell the product to the Canadian population.

At the time that a new drug is introduced to the Canadian market, the drug manufacturer may submit a request to a provincial program for consideration for possible coverage. In general, only drug products that are valid therapeutic agents, with proven clinical effectiveness, are considered for coverage by governmental plans. The drugs that are included on federal, provincial and territorial formularies or drug benefit lists are generally selected by a committee including family doctors, geriatricians, pharmacists and drug information specialists. Governmental drug insurance plans provide payment only for drugs that are on an approved list.

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(16) Yukon, Pharmacare, http://www.hss.gov.yk.ca/prog/hs/insured/pharmacare.html.

(17) Northwest Territories, Seniors Benefit, http://www.hlthss.gov.nt.ca/Features/Programs_and_Services/progandserv.htm.

Each governmental plan has traditionally had its own individual formulary listing for drugs approved for coverage. For example, the federal NIHB Drug Benefit List is published once a year, in April, with updates generally every three months. The list includes over 200 pages of drug products deemed eligible for benefits as cost-effective drug therapy. In Alberta, seniors are eligible for the 3,600 medications listed in the Alberta Health and Wellness Drug Benefit List.

The process of approval for sale in Canada and then approval for listing in governmental formularies can create availability problems for seniors. The Canadian Association on Gerontology noted that older persons are more likely than other groups to be excluded or disproportionately under-represented in the evaluation of new drugs.(18) Consequently, there is little knowledge of the efficacy and safety of new drugs for seniors; and when drugs are being selected for inclusion in formularies, there is little evidence of their clinical effectiveness in treating seniors to guide selection.

With regard to the issue of availability in provincial formularies, there is considerable variability in listings of new drugs. One study found that of 148 new products, only Quebec, British Columbia, Manitoba and Saskatchewan listed more than 70% of them. Of these, Quebec had the highest proportion of drugs listed without restrictions – a fact partially attributed to the province's policy of support for the research-based pharmaceutical industry.(19)

In 2001, the First Ministers agreed to a Common Drug Review (CDR) process to reduce duplication of effort in the assessment of pharmaceuticals for listing in publicly funded drug plans in Canada.(20) The intent was to allow public drug benefit programs to focus on the most therapeutically beneficial and cost-effective drugs for the benefit of patients. Each participating federal, provincial and territorial government can decide which drugs it will list, taking into account factors relevant to its jurisdiction (for example, population needs, other drugs already listed in its formulary, or budgetary considerations).

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(18) Canadian Association on Gerontology, "Policy Statement: Seniors and Prescription Drugs," Ottawa, 1999.

(19) Jean-Pierre Gregoire, "Inter-Provincial Variation in Government Drug Formularies," *Canadian Journal of Public Health*, Vol. 92, No. 4, 31 August 2001, p. 307.

(20) Conference of Federal-Provincial-Territorial Ministers of Health, Backgrounder, "The Common Drug Review," Banff, Alberta, 5 September 2002, http://www.hc-sc.gc.ca/english/media/releases/2002/2002_58bk2.htm.

The Canadian Coordinating Office for Health Technology Assessment established a CDR Directorate and began accepting submissions from manufacturers for new chemical entities and new combination productions on 1 September 2003. The CDR process focuses on two factors: clinical (is the drug therapeutically beneficial relative to other drugs or other treatments?) and pharmacoeconomic (what is the total cost of drug therapy for an individual, relative to anticipated quality of life improvements?).(21)

PUBLICLY FUNDED PLANS AND COSTS

Governmental plans are the primary source of drug insurance for Canadian seniors. But the rising cost of treatment with pharmaceuticals has put pressure on governments to contain costs through public policies to manage use. As health care shifts from in-patient to out-patient settings, seniors are facing changes such as restrictions on eligible drugs listed in formularies, cost-sharing mechanisms including co-payments and deductibles, and substitutions of generic for brand-name drugs.

For seniors, the costs associated with drugs, particularly those taken outside of hospitals or long-term care facilities, are a primary concern affecting access and ultimately appropriate use. As the retail price of patented prescription drugs continues to rise, seniors who require specific drugs for treatment may face prohibitive costs. Observers argue that changes to eligibility requirements for governmental insurance plans, combined with user fees such as co-payments on prescriptions, have eroded the public drug coverage for Canadian seniors. In turn, they assert that this has had adverse health and economic consequences for the most price-sensitive groups – low-income and chronically ill people.(22)

A 1999 survey by The Commonwealth Fund found that, while 24% of Canadian seniors had no monthly out-of-pocket expenditures for prescription medicine, 4% spent more than $100 monthly for prescription medicines.(23) Another study funded through the federal

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(21) Canadian Coordinating Office for Health Technology Assessment, Common Drug Review, http://www.ccohta.ca/entry_e.html.

(22) Joel Lexchin and Paul Grootendorst, "Effects of Prescription Drug User Fees on Drug and Health Services Use and Health Status in Vulnerable Populations: A Systemic Review of the Evidence," *International Journal of Health Services*, Vol. 34, No. 1, 2004, pp. 101-122.

(23) Cathy Schoen et al., *The Elderly's Experience with Health Care in Five Nations: Findings from The Commonwealth Fund 1999 International Health Policy Survey*, May 2000, http://www.cmwf.org.

Health Transition Fund suggested that, because Canadians aged 65 years and older are generally participants in provincial or territorial drug insurance plans, less than 4% experience inadequate coverage.(24)

Because the provincial plans vary substantially, the coverage also fluctuates among groups of seniors, depending on place of residence. One recent study of public coverage for seniors found that while provinces such as Ontario, British Columbia and Alberta offered benefits covering between 70 and 85% of persons aged 65 and over, others such as Newfoundland, New Brunswick, Nova Scotia and Prince Edward Island enrolled as few as 35% of this age group.(25)

Several governmental plans establish an income threshold for determining the coverage of a person aged 65 or over. Some provinces link coverage to the GIS provided by the federal government. This means that having any income over the GIS income threshold can be costly to seniors. In Manitoba, for example, only those families with an income of less than $15,000 will have 100% of their eligible prescription drugs paid for by Pharmacare after paying a deductible (based on their income) of between $100 and $325.(26)

In Quebec and Nova Scotia, seniors pay a premium for coverage under the provincial plan. Relatively high annual deductibles, an amount that must be paid before the individual is eligible for reimbursement, are a reality in British Columbia, Saskatchewan, Manitoba, and Ontario. Co-payments, whereby individuals pay a portion of individual prescription costs, are a requirement under most provincial plans. When seniors have to make a co-payment, they may not have full reimbursement coverage.

Recent studies of Canadian seniors have reinforced evidence that increases in out-of-pocket payments can have negative health outcomes for seniors with low and modest incomes. In a study of Montréal seniors, researchers found that increased cost-sharing for prescription drugs used by elderly persons and welfare recipients was followed by reductions in the use of essential drugs and a higher rate of serious adverse events and emergency department

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(24) "Canadians' Access to Insurance for Prescription Medicines: Executive Summary" of a Health Transition Fund (Health Canada) pharmacare project, March 2000 (contracted to Applied Management Consultants, in consultation with the Fraser Group and Tristat Resources), http://www2.itssti.hc-sc.gc.ca/B_Pcb/HTF/Projectc.nsf/ExecSum/NA202/$File/execsum_eng.pdf.

(25) Steven Morgan, Morris Barer, and Jonathan Agnew, "Whither Seniors' Pharmacare: Lessons From (And For) Canada," *Health Affairs*, Vol. 22, No. 3, May/June 2003, p. 50.

(26) Manitoba Pharmacare, http://www.gov.mb.ca/health/pharmacare/index.html.

visits associated with these reductions.(27) Another study examining the comprehensiveness of provincial drug coverage for seniors found substantial variation in out-of-pocket costs for seniors with identical drug consumption and income levels. For low-income seniors with average drug use, annual expenditures ranged from $42 in British Columbia to $497 in Saskatchewan. For those with high drug use, expenditures ranged from $83 in Ontario to $510 in Saskatchewan.(28)

However, most governmental drug plans cover the drugs needed by individuals with certain high-cost diseases. Generally, the plans have a special authorization mechanism to ensure that high-cost drugs are used according to defined clinical criteria. Drugs that are not regular benefits may be considered for a specific patient, usually after review by physicians and pharmacists. Prior approval must be granted to ensure coverage by special authorization. Some drugs are restricted to specific age groups, and in some instances, the plan may cover only seniors. For example, in Alberta, the provincial drug plan has covered the cost of the cancer drug Rituximab for non-Hodgkin's lymphoma only for patients over 60 years of age. Rituximab costs about $25,000 for eight infusions.(29) Remicade, a biologic used for the treatment of rheumatoid arthritis, can cost approximately $12,000 to $17,000 per year. While several provinces now list this drug on their formulary, some offer coverage only through a special restricted access program.(30) Special authorization is also required for clients of the Veterans Affairs Canada Drug Formulary who require this drug.

CONCLUSION

Access to medications is increasingly important as Canadians age. Although Canadian seniors today are considered to be healthier than those in previous generations, chronic diseases and other conditions requiring pharmaceutical treatment have an increasing and costly role in their health care.

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(27) Robyn Tamblyn et al., "Adverse Events Associated with Prescription Drug Cost-Sharing Among Poor and Elderly Persons," *Journal of the American Medical Association*, Vol. 285, No. 4, 24 January 2001, pp. 421-429.

(28) Paul Grootendorst et al., "A Review of the Comprehensiveness of Provincial Drug Coverage for Canadian Seniors," *Canadian Journal on Aging*, Vol. 22, No. 1, Spring 2003, pp. 33-44.

(29) CBC News, "Provinces restrict access to expensive cancer drugs," 5 May 2004, http://www.cbc.ca/stories/2004/05/05/sci-tech/drug_costs040505.

(30) Canadian Rheumatology Association, "CRA releases position statement on use of biologic therapies for rheumatoid arthritis: Unethical not to treat based on economic considerations," Toronto, 3 April 2003, http://www.cra.ucalgary.ca/cra1/announcements/CRA-Biologics-Position-Paper-Release-FINAL.PDF.

Currently, all federal, provincial and territorial jurisdictions in Canada provide specific drug plans with conditions applicable to people 65 years of age and over. The eligibility requirements and the subsequent benefits vary considerably, resulting in differential access by Canadians seniors depending on place of residence and other factors.

Availability of drugs for use by seniors also varies, depending on whether Health Canada's regulatory process authorizes pharmaceutical companies to market a product, and on whether federal, provincial or territorial governmental drug plan administrators approve its inclusion in drug formularies.

Premiums, deductibles and co-payments affect the drug coverage benefits provided by public insurance plans and the subsequent cost of drugs for seniors. While coverage for seniors in Canada has traditionally been generous, there are concerns about erosion of universality and reduced benefits. Canada's ability to sustain, and even increase, coverage will require effective management of expenditures and serious political commitment to public financing.